

APPLICABLE STATUTES, REGULATIONS AND CFR REFERENCE NUMBERS

Section I: Kansas Statutes and Administrative Regulations (copied verbatim from statutes and administrative regulations manuals)

1. K.S.A. 47-0814: In order to promote the public health, safety and welfare, the legislature hereby declares the practice of veterinary medicine is a privilege granted to those persons possessed of the personal and professional qualifications specified in this act.
2. K.S.A. 47-0830(0-s): The Board, in accordance with the provisions of the Kansas Administrative Procedures Act, may revoke or suspend for a time certain the license of, or otherwise limit, condition, reprimand, restrict, deny a license, or assess a fine not to exceed \$2000 to any licensed veterinarian for any of the following reasons:
 - O: unprofessional conduct as defined in rules and regulations adopted by the Board which includes, but is not limited to the following:
 - S: The use, prescription, administration, dispensing or sale of any veterinary prescription drug or the prescription of an extra label use of any over the counter drug in the absence of the veterinarian-client-patient relationship.
3. K.S.A. 47-850: Immunity from civil liability for report or investigation limits: No person or entity which in good faith, reports or provides information or investigates any veterinarian as authorized by K.S.A. 47-847 and K.S.A. 47-848, and amendments thereto, shall be liable in a civil action for damages or other relief arising from the reporting, providing information, or investigation except upon clear and convincing evidence that the report or the information was completely false, or that the investigation was based on false information, and that the falsity was actually known to the person making the report, providing the information or conducting the investigation at the time thereof.
4. K.A.R. 70-7-1(k): The veterinarian shall ensure that a separate written ledger is maintained when a controlled substance is dispensed.
5. K.A.R. 70-7-1(l): If controlled drugs are used, the veterinarian shall ensure that a locked area for the storage of controlled substances is provided.
6. K.A.R. 70-7-1(j): The veterinarian shall ensure that each dose of a medication administered is properly recorded on the patients medical record. All drugs shall be administered and dispensed only upon the order of a licensed veterinarian.
7. K.A.R. 70-7-1(0-2): A veterinarian may delegate only those activities within the practice of veterinary medicine to an employee which are consistent with that persons training, experience and professional competence. A veterinarian shall not delegate any of the following:
 - A: the activities of diagnosis
 - B: performance of any surgical procedure
 - C: prescription of any drug, medicine, biologic, apparatus, application, anesthesia or other therapeutic or diagnostic substance or technique

Section II: Federal Regulations: (taken from the Code of Federal Regulations, April 1, 1999 revision)

- 1301.31(a): Time for application for registration:
Any person who is required to be registered and who is not so registered may apply for registration at any time.
- 1301.23(a): Separate registrations for separate locations:
A separate registration is required for each professional practice at one general physical location where controlled substances are distributed or dispensed by a person.
- 1301.23(b-3): Separate registrations for separate locations:
The following locations shall be deemed not to be places where controlled substances are distributed or dispensed:

An office used by a practitioner who is registered at another location, where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at such office, and where no supplies of controlled substances are maintained.

- 1301.24(b): Exemption of agents and employees; affiliated practitioners:
An individual practitioner, as defined in 1304.02 of this chapter, who is an agent or employee of another practitioner registered to dispense controlled substances, may, when acting in the usual course of employment, administer and dispense (other than by issuance of prescription) controlled substances under the registration of the employer or principal practitioner in lieu of being registered himself. For example, a staff physician employed by a hospital need not be registered individually to administer and dispense, other than by prescribing controlled substances within the hospital.
- 1301.62: Termination of registration:
The registration of any person shall terminate if and when such person dies, ceases legal existence, or discontinues professional practice. Any registrant who ceases legal existence or discontinues professional practice shall notify the administrator promptly of such fact.
- 1301.75(b): Physical security controls for practitioners:
Pharmacies and institutional practitioners (as defined in 1304.02e of this chapter), may dispense such substances in such a manner as to obstruct the theft or diversion of the controlled substance.
- 1301.75: Physical security controls for practitioners:
DEA Diversion Investigators universally contend that no vehicle by itself offers enough physical security to be acceptable for controlled substance storage.
- 1301.76(b): Other security controls for practitioners:
The registrant shall notify the field division office of the DEA in his area of the theft or significant loss of any controlled substance upon discovery of such loss or theft. The registrant shall also complete a DEA form 106 regarding such loss or theft.
- 1301.90: Employee screening procedures:
- a. It is the position of the DEA that the obtaining of certain information from non-practitioners is vital to fairly assess the likelihood of an employee committing a drug security breach. The need to know this information is a matter of business necessity, essential to overall controlled substance security. In this regard, it is believed that conviction of crimes and unauthorized use of controlled substances are activities that are proper subjects for inquiry.
 - b. Question to prospective employees: "Within the past five years, have you been convicted of a felony or within the past two years any misdemeanor or are you presently formally charged with committing a criminal offense?"
 - c. Question to prospective employees: "In the past three years, have you ever knowingly used any narcotics, amphetamines or barbiturates other than those prescribed to you by a physician? If the answer is yes, please furnish details.
- 1304.03(b): Persons required to keep records and file reports:
A registered individual practitioner is required to keep records of controlled substances in Schedules II-V which are dispensed, other than by prescribing or administering in the lawful course of professional practice. Note this statute suggesting no record keeping for administering is in direct conflict with United States Code (USC) 21(802)(10) which equates dispensing and administering.
- 1306.04(a): Purpose of issue of prescription:
A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual for the purpose of general dispensing to patients.
- 1306.05(a): Manner of issuance of prescriptions:
All prescriptions for controlled substances shall be dated as of and signed on the day when issued and shall bear the full name and address of the patient, drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner. A practitioner may sign a prescription in the same manner he would sign a check or legal document (e.g., J.H. Smith or John H. Smith)

Where an oral prescription is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescriptions may be prepared by the secretary or agent for signature by the practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the laws and regulations. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by these regulations.

- 1306.06: Requirement of a prescription:
A pharmacist may dispense directly a controlled substance in Schedule II only to a written prescription signed by the practitioner.
- 1306.11(a): Requirement of a prescription:
A prescription of Schedule II controlled substances may be transmitted by the practitioner or practitioner's agency to a pharmacy via facsimile equipment, providing the original signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance.
- 1306.11(b): Requirement of a prescription:
An individual practitioner may administer or dispense directly a controlled substance listed in Schedule II in the course of his professional practice without a prescription.
- 1306.13: Partial filling of a prescription:
The partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription (or a written record of the emergency oral prescription). The remaining portion of the prescription may be filled within 72 hours of the first partial filling. However, if the remaining portion is not or cannot be filled within the 72 hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.
- 1306.11(d): Requirement of a prescription:
In the case of an emergency situation, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization of a prescribing practitioner provided that:
- A: The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period.
 - B: The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in 1306.05, except for the signature of the prescribing individual practitioner.
 - C: Within 72 hours after authorizing an emergency oral prescription, the prescribing practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacy. In addition to conforming to the requirements of 1306.05, the prescription shall have written on its face "authorization for emergency dispensing" and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail but if delivered by mail, it must be postmarked within the 72 hour period.
- 1306.22(a-4): Refilling of prescriptions:
The prescribing practitioner must execute a new and separate prescription of any additional quantities beyond the five refill, six month limitation.
- 1306.21: Requirements of a prescription:
A pharmacist may dispense directly a controlled substance listed in Schedule III or IV pursuant to either a written prescription signed by a practitioner or a facsimile of a written signed prescription, signed prescription, signed prescription transmitted by the practitioner or the practitioner's agent to the pharmacy, or pursuant to an oral prescription made by an individual practitioner.
- 1306.31: Requirement of a prescription:
A pharmacist may dispense directly a controlled substance listed in Schedule V pursuant to a prescription as required for controlled substances listed in Schedules III and IV in 1306.21.
- 1306.22(a): Refilling of prescriptions:
No prescription for a controlled substance listed in Schedule III or IV shall be filled or refilled more than six (6) months after the date on which such prescription was issued, and no such prescription authorized to be refilled may be refilled more than five (5) times. The following information must be retrievable by the pharmacist: prescription number consisting of the name and dosage form of the controlled substance, the date filled or refilled, the quantity

dispensed, initials of the dispensing pharmacists for each refill, and the total number of refills for that prescription. The prescribing practitioner may authorize additional refills of Schedule III or IV controlled substances on the original prescription through an oral refill authorization transmitted to the pharmacists provided the following conditions are met:

- A: The total quantity authorized, including the amount of the original prescription does not exceed five refills nor extend beyond six months from the date of issue of the original prescription.
- B: The pharmacists obtaining the oral authorization records on the reverse of the original the date, quantity of refill, number of refills additionally authorized, and initials the prescription showing who received the authorization from the prescribing practitioner who issued the original prescription.
- C: The quantity of each additional refill authorized is equal to or less than the quantity authorized for the initial filling of the original prescription.

1304.12(b): Initial inventory date:
In the event a person commences business with no controlled substances on hand, he shall record this fact as his initial inventory.

1304.04(f): Maintenance of records and inventories:
Each registered practitioner shall maintain inventories and records of controlled substances as follows:
A: Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant.

1304.15(c): Inventories of dispensers:
The inventory shall include the following information for each controlled substance in finished form:
A: the name of the substance
B: each finished form of the substance (example: 10mg tablets or 10mg/ml)
C: the number of units or volume of each finished form in each commercial container (example: 100 tablet bottle or 10ml vial)
D: the number of commercial containers of each such finished form (example: 4-100 tablet bottles or 4-10ml vials)

1304.12(a): Initial inventory date:
Each person required to keep records who is registered after May 1, 1971 shall take a biennial inventory of all stocks of controlled substances from that date on.

1304.17: Inventories of dispensers:
In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser shall do as follows:
A: If the substance is listed in Schedule I or II, he shall make an exact count or measure of the contents
B: If the substance is listed in Schedule III-V, he shall make an estimated count or measure of the contents, unless the container holds more than 1000 tablets or capsules in which he must make an exact count of the contents.

1304.11: General requirements for inventories:
Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken. Controlled substances shall be deemed on hand if they are in the possession or under control of the registrant, including substances returned by a customer, substances ordered by a customer and not yet invoiced, substances stored in a warehouse on behalf of the registrant, and damaged, defective or impure substances awaiting disposal.

1304.23: Records for dispensers:
Each person registered to dispense controlled substances and required to keep records shall maintain records with the following information for each controlled substance:
A: the name of the substance
B: each finished form and number of units or volume of finished form in each commercial container
C: the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser

D: The number of units or volume of such finished forms and or commercial containers disposed of in any manner by the registrant, including the date and manner of disposal and the quantity of the substance in finished form disposed of.

1304.22(ix)(c): Records for manufacturers, distributors, dispensers, researchers, importers and exporters:

Each person registered or authorized to manufacture, distribute, dispense, import, export, or conduct research with controlled substances shall maintain records within the information listed below:

A: (ix): The quantities distributed or disposed of in any other manner by the registrant, including the date and manner of distribution or disposal, the name, address and registration number of the person to whom distributed, and the quantity distributed or disposed of.